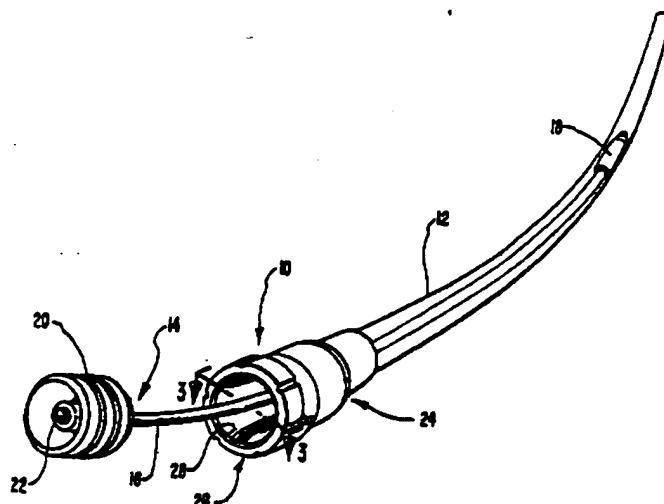




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/00		A1	(11) International Publication Number: WO 92/11880 (43) International Publication Date: 23 July 1992 (23.07.92)
(21) International Application Number: PCT/US91/09699 (22) International Filing Date: 23 December 1991 (23.12.91)			(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent).
(30) Priority data: 633,975 26 December 1990 (26.12.90) US			
(71) Applicant: CARDIOPULMONICS, INC. [US/US]; 5060 West Amelia Earhart Drive, Salt Lake City, UT 84116 (US).			Published <i>With international search report.</i> <i>With amended claims.</i>
(72) Inventors: BERRY, Gaylord, L ; 3020 East 3135 South, Salt Lake City, UT 84109 (US). KERBY, Lynn ; 1623 Casper Road, Draper, UT 84020 (US).			
(74) Agents: NYDEGGER, Rick, D. et al.; Workman, Nydegger & Jensen, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).			

(54) Title: ROTATABLY ACTUATED CONSTRICTING CATHETER VALVE



(57) Abstract

A catheter valve (10) which can be used to effect selective closure of a catheter lumen in order to control fluid flow through the catheter once the catheter is inserted into a patient's body. The apparatus has a valve body with a hub (24) which is joined to the catheter, and a rotatable cap (26) which is joined to the hub (24). An elastomeric sleeve (38) is positioned in an opening (28) through the interior of the valve body. One end of the elastomeric sleeve (38) is joined to the rotatable cap (26) while the other end of the elastomeric sleeve (38) is joined to the hub (24). When the cap (26) is rotated in one direction to a first position, the circular opening (28) of the sleeve (38) is fully opened. When the cap (26) is rotated in the opposite direction to a second position, the elastomeric sleeve (38) is twisted intermediate the two ends so as to ultimately effect closure of the circular opening (28).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BP	Burkina Faso	GB	United Kingdom	MW	Malawi,
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland	KR	Republic of Korea	SE	Sweden
CI	Côte d'Ivoire	LJ	Liechtenstein	SN	Senegal
CM	Cameroun	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Tchad
DE	Germany	MC	Monaco	TC	Togo
DK	Denmark			US	United States of America

1 ROTATABLY ACTUATED CONSTRICTING CATHETER VALVE

BACKGROUND5 1. Field of the Invention

The present invention relates to an apparatus for a catheter valve which can be used to limit or prevent the loss of body fluid from a patient's body when the catheter is introduced into the patient's body, or which can be used to otherwise control the injection or removal of fluids through the catheter.

10

15 2. Technological Background

There are many types of medical devices which must be inserted into a patient's body, such as tubes, catheters, needles, introducer sheathes and the like. As used herein, the term "catheter" is intended to embrace within its scope any devices through which fluids are intended to be injected into a patient's body or through which there is the potential for removal or loss of body fluid from the patient's body, including by way of example but not limitation, tubes, catheters, needles, or introducer sheathes through which catheters, needles or other medical devices can be introduced into a patient's body.

20 When using such catheter-type devices, it is typically necessary or desireable to either control the injection of fluids into the patient's body or to control, limit or prevent fluids from escaping through the lumen of the catheter-type device. To this end, there are many types of clamping or valving apparatus which have been devised. For example, there clamps or hemostats which can be placed on the outside and used to open or close tubes or catheters by pinching or collapsing the walls, thereby controlling fluid flow through the tube or catheter either into or out of the patient's body. These types of exterior clamps or hemostats are typically intended to maintain such tubes or

30
35

1 catheters either fully open or fully closed. However,
there are some circumstances in which it would be
desirable to effect only partial closure of the lumen of
the tube or catheter to permit reduced fluid flow. There
5 are other types of circumstances where constriction of the
lumen of such a tube or catheter must be effected in a
manner so as to prevent loss of blood or other body fluid
as another medical device is introduced through the tube or
catheter into the patient's body.

10 It would be highly advantageous to have a valve which
is capable of being used for any or all such types of fluid
control through a catheter-type device.

BRIEF SUMMARY OF THE INVENTION

15 The present invention is directed to a novel apparatus
for a catheter valve which can be used to effect selective
closure of a catheter lumen in order to control fluid flow
through the catheter lumen once the catheter is inserted
into a patient's body. In a preferred embodiment of the
20 invention, the valve body has a hub which is joined to a
catheter-type device and a rotatable cap which is joined to
the hub. An elastomeric sleeve is positioned in an opening
through the interior of the valve body and one end of the
elastomeric sleeve is joined to the rotatable cap while the
25 other end of the elastomeric sleeve is joined to the hub.
When the cap is rotated in one direction to a first
position, the circular opening of the sleeve is fully
opened. When the cap is rotated in the opposite direction
to a second position, the elastomeric sleeve is twisted
30 intermediate the two ends so as to ultimately effect
closure of the circular opening of the sleeve when the cap
is rotated to the second position. Due to the elastomeric
properties of the sleeve, the circular opening of the
elastomeric sleeve tends to be uniformly constricted as the
35 cap is rotated to effect closure. The catheter valve

1 the present invention can be operated to effect full
opening or full closure of the circular opening through the
valve body and can also be operated to effect variable
constriction of the circular opening or to engage the
5 circumference of a tube or other medical device inserted
through the circular opening so as to prevent fluid flow
from passage around the circumference of the medical
device.

10 Various advantages of the invention will be apparent
from the drawings, description and claims which follow, or
may be learned by the practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The invention will be described with additional detail
and specificity through the use of the accompanying
drawings which are briefly summarized below. The drawings
and accompanying detailed description depict the presently
preferred embodiment and presently understood best mode of
practicing the invention but are not otherwise to be
20 considered as limiting of the invention's scope, which is
set forth in the claims and which are intended to embrace
within their scope equivalent instrumentalities or
combinations.

25 In the drawings, Figure 1 is a perspective illustration
showing the valve of the present invention as used with a
catheter-type device, as for example an introducer sheath,
with an obturator that is inserted into the introducer
sheath. In Figure 1 the catheter valve of the present
invention is shown with the valve in a fully open position.

30 Figure 2 is a perspective illustration showing the
catheter valve of the present invention rotated to effect
closure of the circular opening through the valve body so
as to prevent fluid from flowing through the valve body
around the obturator.

1 Figure 3 is an enlarged cross-sectional view taken
2 along line 3-3 of Figure 1.

3 Figure 4 is an enlarged cross-sectional view taken
4 along line 4-4 of Figure 2.

5 Figure 5 is a cross-sectional view similar to that of
6 Figure 4, but showing a smaller diameter obturator,
7 catheter or tube and particularly illustrating the manner
8 in which the circular opening of the catheter valve is
9 uniformly and variably constricted to effect closure about
10 the circumference of the device.

11 Figure 6A is an elevated side view of the catheter
12 valve of the present invention which illustrates the
13 rotatable valve cap at a first position wherein the
14 circular opening of the valve body is fully open as
15 illustrated in the corresponding elevated end view of
16 Figure 6B.

17 Figures 6C and 6D are elevated side and end views, res-
18 pectively, which particularly illustrate the rotatabl
19 valve cap rotated to an intermediate position so as to
20 effect partial closure of the circular opening.

21 Figures 6E and 6F are elevated side and end views, res-
22 pectively, which particularly illustrate the rotatable
23 valve cap rotated to a second position to effect full
24 closure of the circular opening through the valve body.

25

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference is now made to the drawings wherein lik
parts are designated with like numerals throughout.

Referring first to Figure 1, the catheter valve of th
present invention is generally designated at 10. For
purposes of illustration only, the valve 10 is illustrated
as being coupled at one end of an introducer sheath 12. In
the case of the particular introducer sheath 12 which is
illustrated in Figure 1, the sheath 12 is design d
particularly for ins rtion into the right jugular vein of

35

1 a patient in order to provide access to the patient's vena cava for purposes of introducing an in vivo blood oxygenation device. Also illustrated in connection with the introducer sheath 12 is an obturator which is generally 5 designated at 14 and which comprises a rod-like elongated member 16 with a tip 18 connected thereto at one end (the distal end) and a gripping means 20 connected thereto at the other end (the proximal end). The obturator 14 adds 10 stability to the sheath 10 and provides a blunt,atraumatic tip 18 to facilitate the insertion of the sheath 12 into a patient's venous system. Obturator 14 is also typically provided with a small diameter bore 22 that runs through the length of the elongated member 16 and through which a guide wire (not shown) may be threaded and which can be 15 later used to aid in guiding the entry and positioning of a medical device such as an in vivo blood oxygenation device.

It should be understood that the sheath 12 and obturator 14 have been illustrated merely to show a typical 20 application for which the valve of the present invention can be advantageously utilized, but is not otherwise intended to be limiting of the scope of the invention. The valve 10 may be advantageously used with any one of a variety of different types of tubes for administration of 25 parenteral fluids, catheters for insertion into the arterial, venous or other parts of a patient's body or could be used in connection with various types of needles or other introducer sheath apparatus. Thus, as noted above, the valve of the present invention is intended to be 30 used in connection with any such catheter-type device through which it is necessary or desireable to control, limit or prevent infusion or withdrawal of any type of fluids into or out of a patient.

With further reference to Figure 1, in the presently 35 preferred embodiment of the invention as illustrated in the

1 drawings, the valve comprises a means for defining a valve body with an opening therethrough which communicates with the interior lumen of the sheath or catheter type device to which it is connected. In the preferred embodiment, the
5 means for defining the valve body is comprised of a hub means generally designated at 24 for joining the valve body to the elongated sheath 12 and is also comprised of a cap means as generally designated at 26 for rotatably joining said hub means. A circular opening 28 is provided through
10 the interior of the valve body so as to provide fluid flow through the interior of the valve body. The circular opening 28 is shown in greater detail in Figure 3.

With further reference to Figure 3, in the presently preferred embodiment of the invention as illustrated, the
15 hub means 24 is comprised of an outer cylindrical sleeve clamp 30 and an inner cylindrical sleeve clamp 32. Similarly, the rotatable cap means 26 is also comprised of an outer cylindrical sleeve clamp 34 and an inner cylindrical sleeve clamp 36. In a further aspect of the
20 invention, the valve is comprised of a means for constricting the circular opening 28 through the valve body as the cap means 26 is rotated relative to the hub means 24 such that when the cap means 26 is rotated to a first position the means for constricting does not obstruct the
25 circular opening 28, and when the cap means 26 is rotated in an opposite direction to a second position, the means for constricting effects closure of the circular opening 28.

In the presently preferred embodiment, as shown best in
30 Figures 2-4 taken together, the means for constricting the circular opening of the valve body is comprised of an elongated, cylindrical elastomeric sleeve 38. Sleeve 38 has one end 42 which is clamped and held firmly between the outer and inner cylindrical sleeve clamps 34 and 36 of rotatable cap means 26, whereas the other end 44 of the
35

1 elastomeric sleeve 38 is firmly clamped and held between
the outer and inner cylindrical sleeve clamps 30 and 32 of
the hub means 24. Accordingly, when the cap means 26,
5 including the outer and inner cylindrical sleeve clamps 34
and 36 are rotated while the outer and inner cylindrical
sleeve clamps 30 and 32 of the hub means 24 are held
stationary, the elastomeric sleeve 38 is twisted
10 intermediate the two ends 42 and 44 of sleeve 38 so as to
effect closure of the opening 28 which is otherwise
provided through the sleeve 38. Thus, as shown best in
Figures 2 and 4, the elastomeric sleeve 38 will be
15 collapsed upon the elongated member 16 of the obturator to
provide a fluid-tight seal thereby preventing any fluid
from flowing through the opening 28 in the space around the
elongated member 16 of the obturator. In the alternative,
20 if an obturator or other tube or catheter-type device is
not inserted through the circular opening 28 of the valve
body, the elastomeric sleeve 38 can be completely collapsed
to effect full closure as illustrated, for example, in the
elevated end view of Figure 6F.

With continued reference to the cross-sectional views
of Figures 3 and 4, the outer cylindrical sleeve clamp 34
of the rotatable cap means 26 is provided with a square
shoulder 46. The vertical edge of the square shoulder 46
25 provides a supporting abutment for a circular rim 48 that
is formed on the inner cylindrical sleeve clamp 36. A
portion 50 of the inner cylindrical sleeve clamp 36 extends
beneath the horizontal edge of the square shoulder 46 of
outer cylindrical sleeve clamp 34. The end 42 of
30 elastomeric sleeve is firmly clamped and held between the
horizontal edge of shoulder 46 and the portion 50 of inner
cylindrical sleeve clamp 36 that extends therebeneath.

The opposite end 44 of the elastomeric sleeve 38 is
firmly held and clamped between a horizontal extension 52
35 of the outer cylindrical sleeve clamp 30 and a lower

horizontal extension 54 of the inner cylindrical sleeve clamp 32 of the hub means 24. The inner cylindrical sleeve clamp 32 of the hub means 24 is also comprised of a square shoulder 56 and the vertical edge of the square shoulder 56 provides a supporting abutment for the end of the horizontal extension member 52. The inner cylindrical sleeve clamp 32 also provides an upper horizontal extension member 58 which projects beneath an overhanging lip 60 on the outer cylindrical sleeve clamp 34 of the rotatable cap means 26. Further, the inner cylindrical sleeve clamp 36 of the rotatable cap means 26 also has a horizontal support member 62 which provides a rotational bearing surface upon which the upper horizontal extension member 58 rests. The outer and inner cylindrical sleeve clamps 34 and 36 of the rotatable cap means 26 are firmly bonded or otherwise secured together so as to provide a unitary piece which rotates relative to the inner and outer cylindrical sleeve clamps 30 and 32 of the hub means 24.

Because of the rotatable bearing surface provided by the horizontal support member 62 which supports the horizontal extension member 58, the outer cylindrical sleeve clamp 34 can be grasped and rotated in either direction therefore rotating both the inner and outer cylindrical sleeve clamps 34 and 36 relative to the outer and inner sleeve clamps 30 and 32 of the hub means 24. The effect of this rotational movement will be to twist the elastomeric sleeve 38 such as illustrated at point 40 thereby collapsing the elastomeric sleeve 38 at that point. In this manner, the elastomeric sleeve 38 will serve as a means for constricting the circular opening in an essentially uniform, variable fashion, as illustrated best in the elevated end views of Figures 6B, 6D and 6F.

In Figure 6B the elastomeric sleeve is not rotated so that the circular opening 28 is fully open. In Figure 6D the rotatable cap means has been partially rotated to

1 effect partial closure of the circular opening 28 by
2 causing a partial collapse of the elastomeric sleeve 38 at
3 point 40 due to the twisting effect of rotating one end of
4 the sleeve 38 relative to the other. In Figure 6F full
5 closure of the circular opening has been effected by
6 completely rotating one end of the elastomeric sleeve 38
7 relative to the other until the elastomeric sleeve has been
8 completely twisted to a closed condition.

9 As will be further appreciated in reference to Figures
10 2-5, the elastomeric sleeve 38 can also provide effective
11 closure and fluid-tight seal against an obturator or other
12 tube-like device which is inserted through the circular
13 opening 28. In the case of Figures 2-4, the elongated rod-
14 like member 16 of the obturator can be left free to slide
15 in or out of the circular opening when the elastomeric
16 sleeve 38 is in an open or partially closed condition, or
17 alternatively the elastomeric sleeve 38 can be twisted to
18 effect closure and to provide a fluid-tight seal against
19 the elongated rod-like member 16 by the aforementioned
20 rotational movement of the cap means 26 relative to the hub
21 means 24. Figure 5 illustrates how a tube or rod of
22 smaller diameter such as illustrated at 16A can also be
23 effectively sealed within the circular opening 28 by
24 twisting one end of the elastomeric sleeve 38 relative to
25 the other.

26 With further reference to Figures 3 and 4, the outer
27 cylindrical sleeve clamp 30 is tapered at portion 64 and
28 terminates in a cylindrical inner collar 66. A cylindrical
29 outer collar 68 fits over the inner collar 66 and is used
30 to clamp the end of the sheath or other catheter-like
31 device 12 between the two so as to join the hub means 24 to
32 the sheath or catheter-like device 12.

33 The manner of operating the valve of the present
34 invention is best understood in reference to Figures 6A-6F.
35 As will be seen best in the elevated side views of Figures

1 6A, 6C and 6E, the outer cylindrical sleeve clamp 34 also
serves as a cap which can be rotated relative to the hub of
the valve. The rotatable cap has a lip 60 which extends
5 partially around the circumference of the valve. At one
end of the lip 60 there is a notch 72 provided which
defines a first position for the rotatable cap. At the
other end of the lip 60, as shown best in Figure 6E, there
is a second notch 76 which is formed, which defines a
10 second position of the rotatable cap. A post 70 (see also
Figures 3 and 4) is anchored in the inner cylindrical
sleeve clamp 32 of the hub means.

Post 70 in conjunction with the lip 60 serves as a stop
means for limiting rotational movement of the rotatable cap
in either direction of rotation. Accordingly, when the
15 rotatable cap is rotated to the position shown in Figure
6A, the elastomeric sleeve 38 is fully open so as not to
obstruct the circular opening 28 of the valve body. When
the rotatable cap is partially rotated as shown in Figure
6C the elastomeric sleeve 38 will partially constrict as it
20 begins to twist at the intermediate portion of its length.
Thus, as shown in Figure 6D the circular opening 28 will be
partially obstructed when the cap is rotated to the
position of Figure 6C. When the rotatable cap is fully
25 rotated in the opposite direction to the notch 76 so that
the rotatable cap will be held in that position by the post
70, the elastomeric sleeve 38 will effect full closure of
the circular opening 28, as shown in Figure 6F. As will be
further appreciated from Figures 6A, 6C and 6E taken
30 together, the rotatable cap has a portion of its length
shortened as illustrated at 74 so as to permit rotation of
the cap relative to the post 70 which provides a stop for
engaging the notched positions 72 or 76.

35 The invention may be embodied in other specific forms
without departing from its spirit or essential
characteristics. The described embodiments are to be

11

1 considered in all respects only as illustrative and not
restrictive. The scope of the invention is, therefore,
indicated by the appended claims rather than by the
foregoing description. All changes which come within the
meaning and range of equivalency of the claims are to be
embraced within their scope.

10

15

20

25

30

35

CLAIMS:

1. A valve for effecting selective closure of a catheter lumen to control fluid flow through the catheter lumen once the catheter is inserted into a patient's body, the valve comprising:

5 means for defining a valve body with an opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means; and

10 means for constricting said opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for constricting does not obstruct said opening, and when said cap means is rotated to a second position, said means for constricting effects closure of said opening.

15

2. A valve as defined in claim 1 wherein said hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

20

3. A valve as defined in claim 2 wherein said cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25

4. A valve as defined in claim 3 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a

30

35

1 second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

5. A valve as defined in claim 2 wherein said hub means further comprises a cylindrical catheter clamp.

10 6. A reflux valve as defined in claims 1 and 2 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

15 7. A reflux valve as defined in claim 6 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

20 a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

8. A valve for controlling fluid flow through a catheter connected to said valve when the catheter is inserted into a blood vessel, said valve comprising:

25 a valve body comprised of a hub means for joining said valve to said catheter and a cap means for rotatably joining to said hub means, said hub means and said cap means each comprising a means for clamping an end of an elastomeric sleeve; and

30 a cylindrical, elastomeric sleeve having one end clamped to said hub means, and having another end clamped to said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to

1 : said hub means to a second position, said elastomeric
5 sleeve is twisted to effect closure of the sleeve.

9. A valve as defined in claim 8 further comprising
5 stop means for limiting rotation of said cap means relative
to said hub means so as to stop said cap means at said
first position when rotated in one direction, and so as to
stop said cap means at said second position when rotated in
an opposite direction.

10

10. A valve as defined in claim 9 wherein said stop
means comprises:

a post anchored in the inner cylindrical sleeve
clamp of said hub means; and

15

a lip extending around a portion of the
circumference of said outer cylindrical sleeve clamp of
said cap means.

20

11. A valve as defined in claim 10 wherein said hub
means further comprises a cylindrical catheter clamp.

25

12. A valve as defined in claim 8 wherein each said
means for clamping an end of said elastomeric sleeve
comprises an outer cylindrical sleeve clamp and an inner
cylindrical sleeve clamp.

30

13. A valve for effecting selective closure of a
catheter lumen to control fluid flow through the catheter
lumen once the catheter is inserted into a patient's body,
the valve comprising:

means for defining a valve body with an opening
therethrough which communicates with said catheter
lumen, said means for defining said valve body
comprising hub means for joining said valve body to

1 said catheter, and cap means for rotatably joining to
said hub means;

5 means for constricting said opening of the valve
body as said cap means is rotated relative to said hub
means, such that when said cap means is rotated to a
first position said means for constricting does not
obstruct said opening, and when said valve body is
rotated to a second position, said means for
constricting effects closure of said opening; and

10 stop means for limiting rotation of said cap means
relative to said hub means so as to stop said cap means
at said first position when the cap means is rotated in
one direction, and so as to stop said cap means at said
second position when the cap means is rotated in an
opposite direction.

14. A valve as defined in claim 13 wherein said hub
means comprises an outer cylindrical sleeve clamp and an
inner cylindrical sleeve clamp.

20 15. A valve as defined in claim 14 wherein said cap
means comprises an outer cylindrical sleeve clamp and an
inner cylindrical sleeve clamp.

25 16. A valve as defined in claim 15 wherein said means
for constricting said opening comprises a cylindrical,
elastomeric sleeve having one end clamped between the inner
and outer sleeve clamps of said hub means, and having
another end clamped between the inner and outer sleeve
30 clamps of said cap means, such that when said cap means is
rotated relative to said hub means to a first position,
said elastomeric sleeve is untwisted and open, and when
said cap means is rotated relative to said hub means to a
second position, said elastomeric sleeve is twisted to
eff ect closur of th sleeve .

17. A valve as defined in claim 16 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

18. A valve as defined in claim 17 wherein said hub means further comprises a cylindrical catheter clamp.

19. A valve for effecting selective closure of a catheter lumen to prevent escape of body fluid through the catheter lumen when a tube is inserted through the catheter lumen and the catheter is inserted into a patient's body, the valve comprising:

means for defining a valve body with a circular opening therethrough which communicates with said catheter lumen, said tube extending through the circular opening into the lumen of said catheter, and said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means; and

means for variably constricting said circular opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for variably constricting said circular opening does not obstruct said circular opening so that said tube is freely slidable through said circular opening and the lumen of said catheter, and such that when said valve body is rotated to a second position said means for variably constricting said circular opening uniformly closes around said tube and frictionally engages said

1 tube to prevent escape of body fluid through said lumen and around said tube through the circular opening.

5 20. A valve as defined in claim 19 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

10

21. A valve as defined in claim 20 wherein said stop means comprises:

 a post anchored in the inner cylindrical sleeve clamp of said hub means; and

15

 a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

20 22. A valve as defined in claim 19 wherein said hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25 23. A valve as defined in claim 22 wherein said cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

30 24. A valve as defined in claim 23 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a

35

18

1 second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

5

10

15

20

25

30

35

AMENDED CLAIMS

[received by the International Bureau on 1 June 1992 (01.06.92);
original claims 1-24 replaced by amended claims 1-24
(8 pages)]

1 1. A valve for effecting selective closure of a catheter lumen to control fluid flow through said catheter lumen once a catheter is inserted into a patient's body, said valve comprising:

5 means for defining a valve body with an inside opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means, and the hub means and cap means each comprising a clamping means; and

10 means for constricting said inside opening of said valve body as said cap means is rotated relative to said hub means and said means for constricting having one end wrapped around and clamped by the clamping means of the hub means, and having another end wrapped around and clamped by the clamping means of the cap means, so as to provide an unobstructed lining along said inside opening of said valve body, such that when said cap means is rotated to a first position said means for constricting does not obstruct said inside opening, and when said cap means is rotated to a second position, said means for constricting effects closure of said inside opening of said valve body.

15 2. A valve as defined in claim 1 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

20 3. A valve as defined in claim 2 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

1

4. A valve as defined in claim 3 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

15

5. A valve as defined in claim 2 wherein said hub means further comprises a cylindrical catheter clamp.

20

6. A reflux valve as defined in claims 1 or 2 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

25

7. A reflux valve as defined in claim 6 wherein said stop means comprises:

30

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

35

8. A valve for controlling fluid flow through a catheter connected to said valve when said catheter is inserted into a blood vessel, said valve comprising:

a valve body having an inside opening, said valve body comprised of a hub means for joining said valve

1

5

10

15

20

25

30

35

to said catheter and a cap means for rotatably joining to said hub means, said hub means and said cap means each comprising a means for clamping an end of a cylindrical elastomeric sleeve, said cylindrical, elastomeric sleeve having one end wrapped around one of said clamping means and clamped to said hub means, and having another end wrapped around the other said clamping means clamped to said cap means, such that when said cap means is rotated relative to said hub means to a first position, said cylindrical elastomeric sleeve is untwisted and open, and provides an uninterrupted seamless lining along said inside opening of said valve body, and when said cap means is rotated relative to said hub means to a second position, said cylindrical elastomeric sleeve is twisted to effect closure of said opening of said valve body.

9. A valve as defined in claim 8 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

10. A valve as defined in claim 9 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

11. A valve as defined in claim 10 wherein said hub means further comprises a cylindrical catheter clamp.

1

12. A valve as defined in claim 8 wherein each said means for clamping an end of said elastomeric sleeve comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

5

10 13. A valve for effecting selective closure of a catheter lumen to control fluid flow through said catheter lumen once a catheter has been inserted into a patient's body, said valve comprising:

15

means for defining a valve body with an inside opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprises hub means for joining said valve body to said catheter lumen, and cap means for rotatably joining to said hub means said catheter lumen, and the hub means and cap means each comprising a clamping means;

20

25 means for constricting said opening of said valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for constricting does not obstruct said opening and said means for constricting having one end wrapped around and clamped by the clamping means of the hub means, and having another end wrapped around and clamped by the clamping means of the cap means, so as to provide an unobstructed lining along said inside opening of said valve body, and when said valve body is rotated to a second position, said means for constricting effects closure of said opening of said valve body; and

30

35 stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when said cap means is rotated in one direction, and so as to stop said

35

1

cap means at said second position when said cap means is rotated in an opposite direction.

5

14. A valve as defined in claim 13 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

10

15. A valve as defined in claim 14 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

15

16. A valve as defined in claim 15 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

25

17. A valve as defined in claim 16 wherein said stop means comprises:

30

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

35

18. A valve as defined in claim 17 wherein said hub means further comprises a cylindrical catheter clamp.

1

19. A valve for effecting selective closure of a catheter lumen and about a tube inserted therethrough to prevent escape of body fluid through said catheter lumen when said catheter is inserted into a patient's body, said valve comprising:

5

means for defining a valve body with a circular opening through the inside of said valve body and which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter lumen, and cap means for rotatably joining to said hub means, and the hub means and cap means each comprising a clamping means; and

10

means for variably constricting said circular opening of said valve body as said cap means is rotated relative to said hub means, said means for variably constricting having one end wrapped around and clamped by the clamping means of the hub means, and having another end wrapped around and clamped by the clamping means of the cap means so as to provide an unobstructed lining along said opening along the inside of said valve body, such that when said cap means is rotated to a first position said means for variably constricting said circular opening seamlessly lines the inside of said valve body but does not obstruct said circular opening so that said tube is freely slidable through said circular opening and the lumen of said catheter, and such that when said valve body is rotated to a second position said means for variably constricting said circular opening uniformly closes around said tube and frictionally engages said tube to prevent escape of body fluid through said catheter lumen and around said tube through said circular opening of said valve body.

20

25

30

35

1

5

20. A valve as defined in claim 19 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

10

21. A valve as defined in claim 20 wherein said stop means comprises:

15

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

20

22. A valve as defined in claim 19 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25

23. A valve as defined in claim 22 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

30

35

24. A valve as defined in claim 23 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a

1

second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

5

10

15

20

25

30

35

1/4

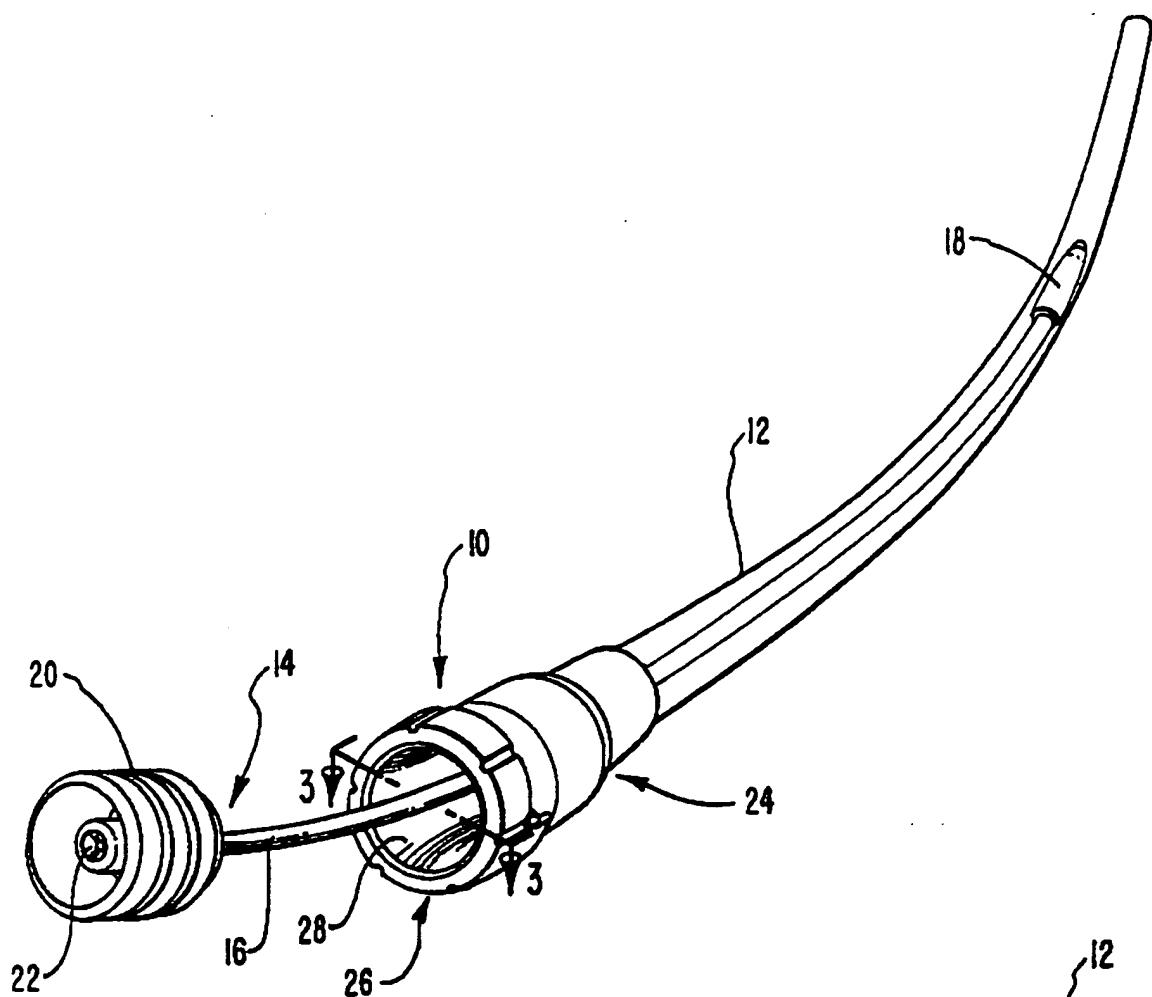


FIG. 1

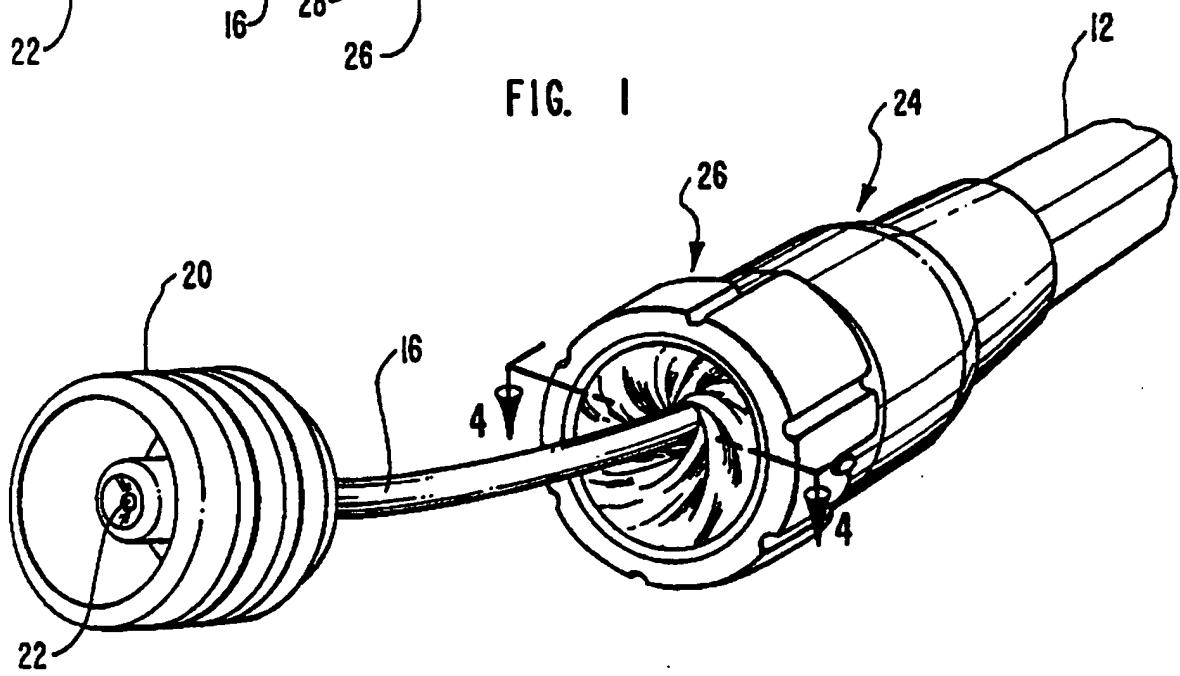


FIG. 2

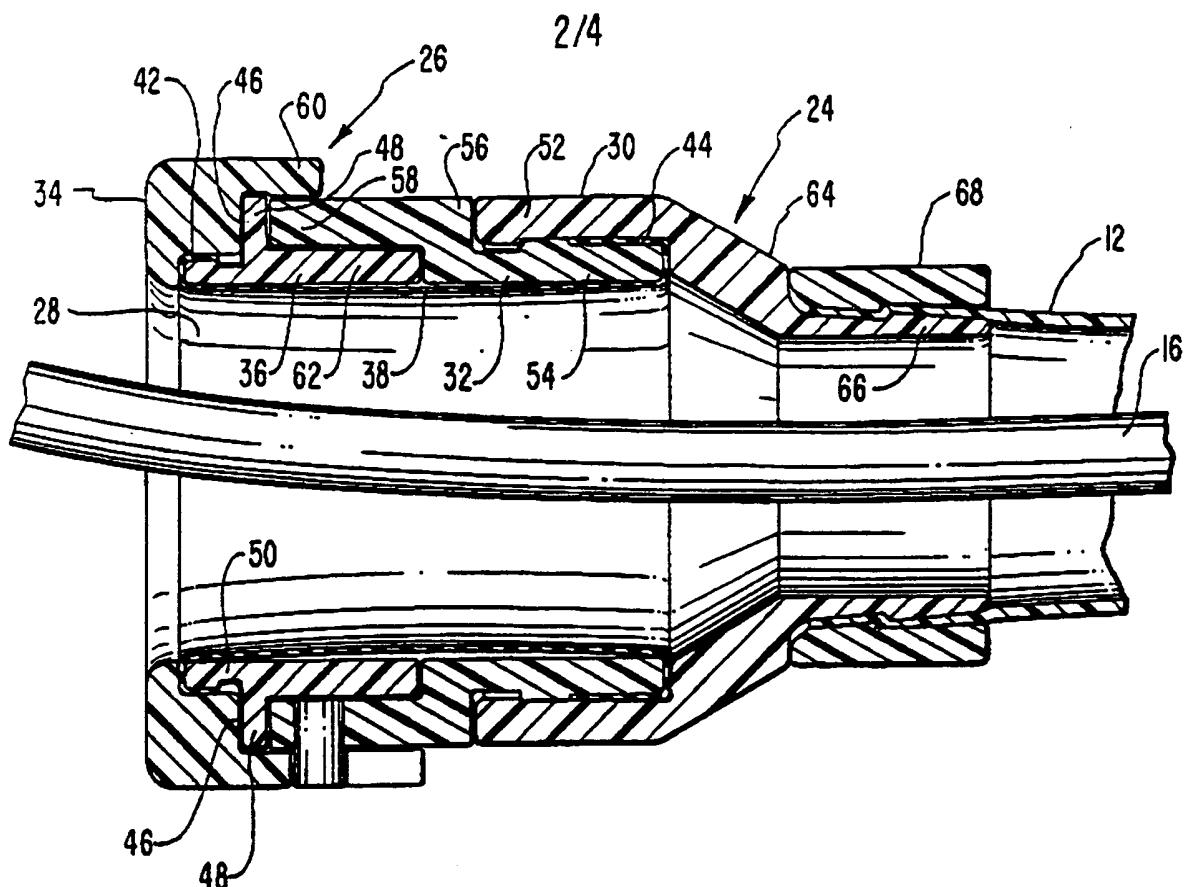


FIG. 3

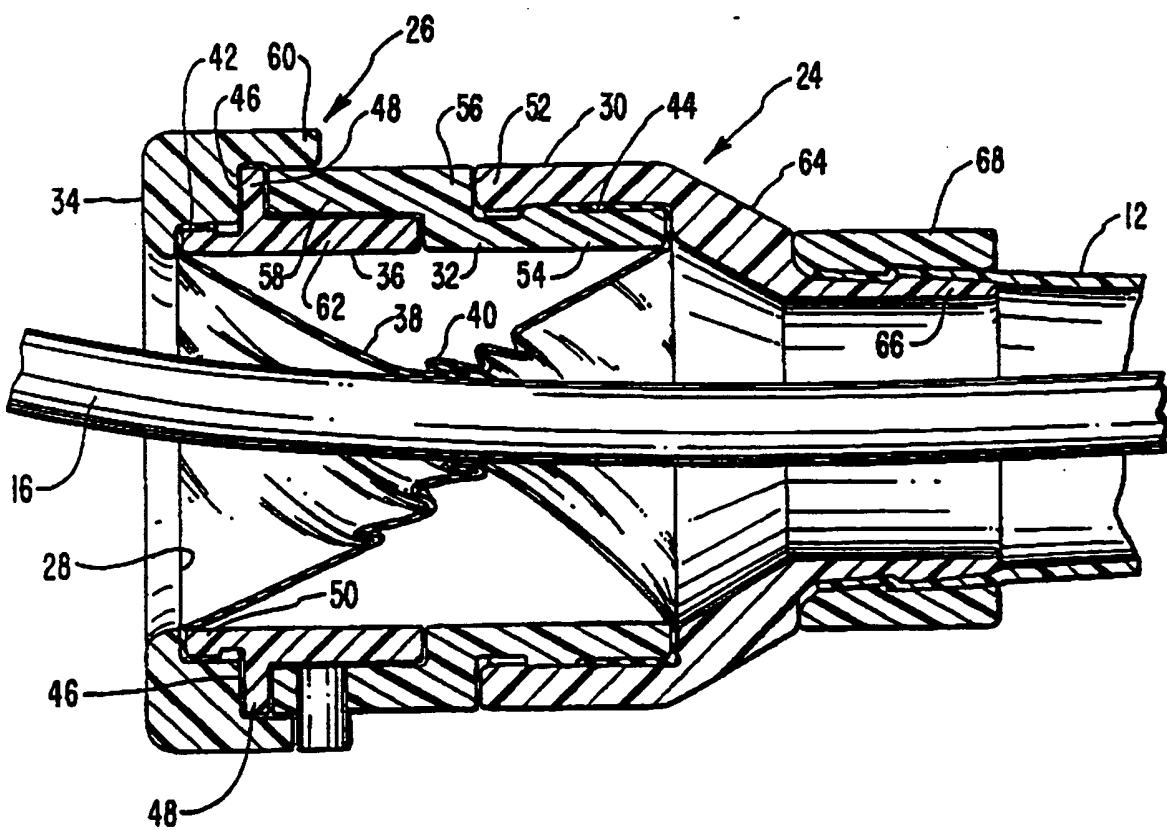


FIG. 4

3/4

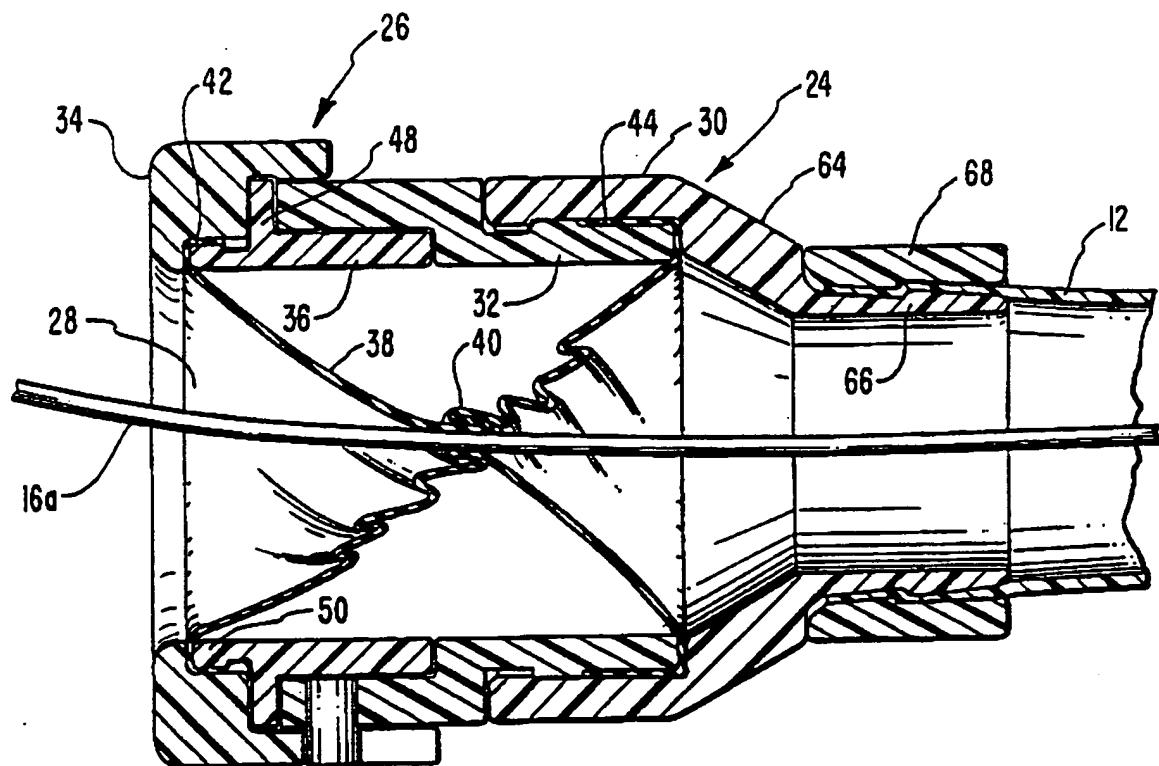


FIG. 5

4/4

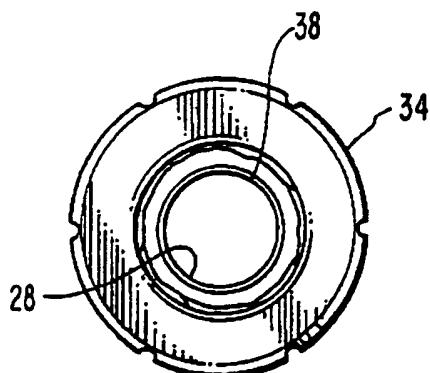


FIG. 6B

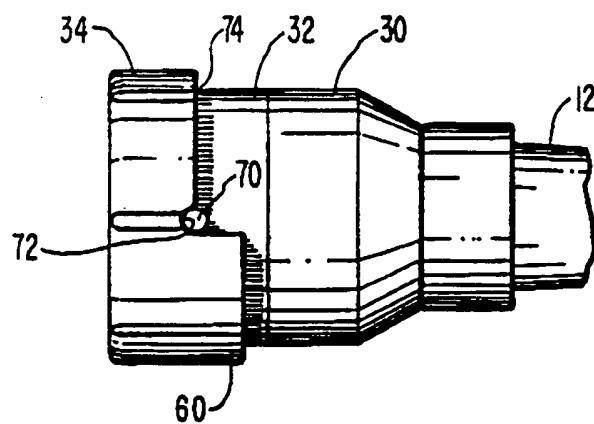


FIG. 6A

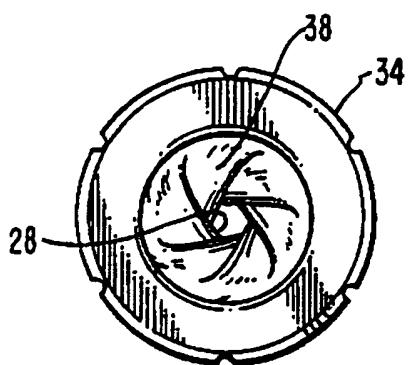


FIG. 6D

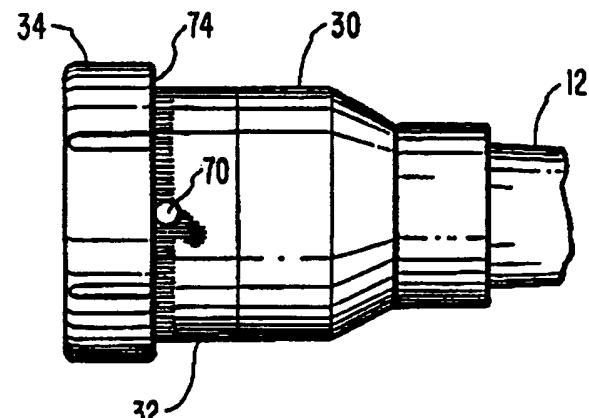


FIG. 6C

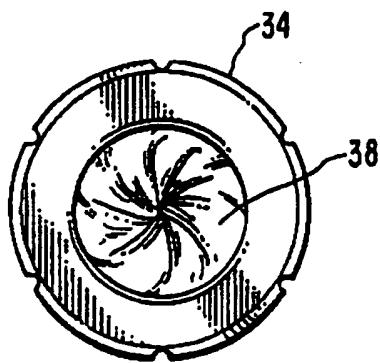


FIG. 6F

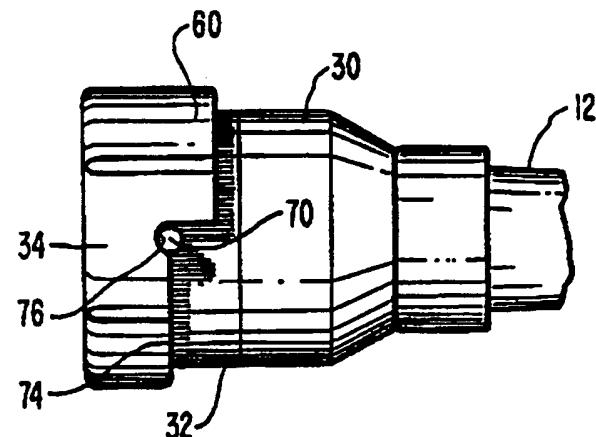


FIG. 6E

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/09699

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 5/00 U.S. CL: 604/248

II. FIELDS SEARCHED

Minimum Documentation Searched ⁷

Classification System	Classification Symbols
U. S.	604/248,256,167,246,169,164,32,237,236,264

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US, A, 4,540,411 (BODICKY) 10 SEPTEMBER 1985	1-5,8,12,19
Y	See the entire document.	22-24
		6,7,9-11,13-18, 20,21
Y	US, A, 3,185,179 (HARALJTUNELIAN) 25 MAY 1965 See Figures 4 and 5.	2-7,9-18,20-24
X	US, A, 4,580,573 (QUINN) 08 APRIL 1986	1, 8, 19
Y	See entire document.	2-7,9-18,20-24
A	US, A, 4,314,555 (SAGAE) 09 FEBRUARY 1982 See entire document.	1-24
A	US, A, 4,978,341 (NIEDERHAUSER) 18 DECEMBER 1990 See entire document.	1-24
A	US, A, 2,844,351 (SMITH) 22 JULY 1958 See entire document.	1-24

⁶ Special categories of cited documents: is

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier document but published on or after the international filing date

"C" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)

"D" document referring to an oral disclosure, use, exhibition or other means

"E" document published prior to the international filing date but later than the priority date claimed

"F" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"G" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"H" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"I" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

Date of Mailing of this International Search Report

28 FEBRUARY 1992

30 MAR 1992

International Searching Authority
ISA/US

Signature of Authorized Officer

JEFFREY A. SMITH

